REMARKS

Applicants respectfully requests entry of the amendments and remarks submitted herein. Claims 1, and 11-18 are amended, claims 7 and 19 are canceled, and claims 20-26 are added. Therefore, claims 1-6 and 8-18, and 20-26 are currently pending.

Interview Summary

Applicant's Representative wishes to thank Examiner Audet for the courtesies extended to her during the telephonic interviews on September 27 and 28, 2006. During the interviews proposed claim amendments were discussed.

Observation

Claim 7 was cancelled, but he claim limitation was left in its entirety. The Examiner requested that the text of the claim be removed from the listing of claims. Applicant has complied with this request.

Claim Rejections under 35 U.S.C. §102(b)

The examiner indicated that claims 1-6 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Viriyakosol et al. (J. Biol. Chem. 2001 276:38044-51).

Claim 1, as currently amended, recites a purified complex consisting of one molecule of endotoxin bound to one molecule of MD-2. Pending claims 2-6 and 8-9 depend directly or indirectly from claim 1.

The Examiner states that the basic and novel characteristic of the claimed invention is MD-2 bound to endotoxin, and that the addition of more than one molecule of either MD-2 or endotoxin does not materially affect the "basic and novel characteristic of the claimed invention." Applicant respectfully asserts that the addition of more than one molecule of either MD-2 or endotoxin does materially affect the basic and novel characteristic of the claimed invention.

In the various Viriyakosol et al. experiments, the LPS was present in the form of an aggregate, and not in the monomeric form, as recited in the pending claims. This is an important difference. Figure 1 of the present specification demonstrates that single as opposed to aggregate

presentation of the endotoxin produces dramatically different results. Please note that the combination of LOS_{agg} with culture medium containing active MD-2 resulted in no cell activation. In contrast, when the inventors incubated LOS:sCD14 with the same culture medium containing sMD-2, the cells were activated. Moreover, it should be noted that it was surprising and unexpected to the inventors when they discovered that the endotoxin was bound to the MD-2 in a monomeric form, and that they were water soluble. As indicated on page 3, lines 9-11 of the present specification, "[s]urprisingly, these complexes, devoid of any other host or microbial molecules, are potent and water soluble, not requiring additional lipid carrier molecules (*e.g.*, serum albumin) for water solubility."

Thus, since Viriyakosol et al. do not teach or suggest all of the features of the claimed invention, Viriyakosol et al. does not anticipate the claimed invention. Further, the resulting product, the claimed monomeric MD-2:endotoxin complex was a surprising and unexpected result given the teachings at the time the application was filed. Accordingly, Applicant respectfully requests withdrawal of this 35 U.S.C. 102(b) rejection of the claims.

Allowable Subject Matter

The Examiner has indicated that claims 11-19 are free of the art. These claims were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the features of the base claim and any intervening claims. These claims have been amended as suggested by the Examiner. Applicants respectfully request that this objection be withdrawn.

CONCLUSION

The Examiner is invited to contact Applicant's Representative at the below-listed telephone number if there are any questions regarding this Response or if prosecution of this application may be assisted thereby. If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 50-3503. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extension fees to Deposit Account 50-3503.

Respectfully submitted,

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By their Representatives,

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Date: 29 September 2006

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